DRUG CONTAINER

The present invention relates to an assembly comprising an injection device having a distal tip on which is mounted an adaptor element, such as a Luer lock adaptor, further comprising a means for preventing the rotation of the adaptor with respect to the distal tip.

In this application, the distal end of a component or of a device is to be understood as meaning the end furthest from the user's hand and the proximal end is to be understood as meaning the end closest to the user's hand. Likewise, in this application, the "distal direction" is to be understood as meaning the direction of injection, and the "proximal direction" is to be understood as meaning the opposite direction to the direction of injection.

Various medical devices are known for transferring and/or storing medical fluids, such as syringes, perfusion and transfusion devices and connectors. It is essential that these various medical devices can be assembled together correctly and securely.

A conventional injection device usually comprises a hollow body forming a container for a medical product the distal end of the body forming the container usually comprises a tip in which an axial passageway is arranged through which the said product is ejected from the container.

The handling of liquid products, in particular for a parenteral administration to a patient which is carried out via a perfusion device, as often in hospitals or in emergency situations, implies, in a general manner, the use of connectors. Such connectors make it possible to seal assemblies of medical devices and provide protection against the contamination of the medical liquid products that they contain.

The connectors, like for example IV (Intra Venous) connectors, are usually connected to the injection device by means of intermediate elements such as adaptors. Usually, these adaptors are first mounted by friction on the distal tip of the injection device: the connector, such as an IV connector, is then mounted on the free end of the adaptor, for example by screwing. In such a step, the adaptors are friction fitted on the distal tip and are supposed to remain immobile, thanks to the friction forces, with respect to the distal tip while the connector is screwed on the adaptor. However, problems have been reported concerning the use of some adaptors with various injection devices: for example, the adaptors do not remain immobile with respect to the distal tip. In particular, the friction forces are not important enough to prevent the adaptor from rotating with respect to the distal tip. It is therefore difficult for the user to determine whether the connector is well fitted in the adaptor or not and, as a consequence, whether the connector is well connected to the distal tip of the injection device. An incorrect connection between the injection device and the connector may cause leaks of product and therefore incorrect doses administered to the patient.

There is therefore a need for an injection device that would allow the reproducible connection between said injection device and an adaptor, so that the user knows when the connector is correctly connected to the injection device via the adaptor.

One aspect of the present invention is an assembly comprising:

an injection device comprising a container for a product, said container comprising a distal tip encompassing a channel providing a passageway for the transfer of said product,

an adaptor comprising a ring mounted onto said distal tip,

characterized in that said assembly further comprises a heat-shrinkable film covering at least part of said container and at least part of said adaptor, said heat-shrinkable film maintaining said adaptor blocked in rotation and in translation with respect to said container when said heat-shrinkable film is in its heat-shrunk condition.

Because at least part of the adaptor is imprisoned within the shrunk film together with at least part of the container, the adaptor is firmly fixed with respect to said container, and therefore to said distal tip and it is prevented from rotating and translating with respect to the distal tip of the injection device. The user can simply screw the connector to the adaptor by grasping in his fingers the assembly via the shrunk film on one hand, and the connector on the other hand. Since the adaptor is not allowed to move with respect to the distal tip of the container, the user is certain to correctly screw the connector to the adaptor and then to the injection device.

In an embodiment of the invention, the ring of the adaptor is mounted on said distal tip by friction.

Preferably, the heat-shrinkable film covers part of said container and part of said adaptor in a continuous way.

In an embodiment of the invention, said heat-shrinkable film is made of a thermoplastic material selected from the group consisting of polyvinyl chloride (PVC), polyethylene terephthalate (PET), oriented polystyrene (OPS), oriented polypropylene (OPP), polylactic acid (PLA) and mixtures thereof. In an embodiment of the invention, the heat-shrinkable film is made of polyvinyl chloride.

The assembly of the invention may further comprise a label imprisoned between said heat-shrinkable film and said container and/or adaptor. In another embodiment of the invention, the assembly comprises a label located on said heat-shrinkable film. Said label may be made of paper and may be printed, for example with information relating to the contents of the container.

In an embodiment of the invention, the assembly further comprises a plug mounted on said adaptor. The plug is removably mounted on the adaptor, for example by friction or by screwing, and it is intended to close access to the adaptor. The heat-shrinkable film may also cover at least part of said plug. In such a case, for example, said heat-shrinkable film is provided with an annular breakable line located on the part of the heat-shrinkable film that covers part of said plug. The annular breakable line needs be broken in order to remove the plug and open the adaptor. The annular breakable line therefore constitutes a tamper evident means of the opening of the adaptor.

In an other embodiment of the invention, said heat-shrinkable film is at least partially glued on at least one of said container or adaptor.

The heat-shrinkable film may also be provided with writing.

Another aspect of the invention is a method for manufacturing an assembly as defined above comprising the following steps:

a°) an injection device comprising a container for a product, said container comprising a distal tip encompassing a channel providing a passageway for the transfer of said product, and a suitable adaptor are provided,

b°) the suitable adaptor is fitted on the distal tip of said injection device,

c°) a heat-shrinkable film, for example under the form of a rectangular sheet, is bonded on the assembly so as to cover at least part of the adaptor and at least part of said container,

d°) the heat-shrinkable film is heated until it shrinks and tightly covers said part of said container and said part of said adaptor so as to maintain said adaptor blocked in rotation and in translation with respect to said container.